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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,052

05/06/2005

Eric Rougemond

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/534,052	Applicant(s) ROUGEMOND ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 2-14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/6/2005</u> | 6) <input type="checkbox"/> Other: ____ |

CLAIMS 1-19 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed May 6, 2005 have been received and entered into the application. Accordingly, claims 9-16 and 18 have been amended. Also, as reflected by the attached, completed copy of form PTO/SB/08A, (1 sheet), the Examiner has considered the references cited by Applicants.

Claim Objection

Claims 2-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 1, from which claims 2-14 depend, is directed to a "Use of fosinopril or a pharmaceutically acceptable salt thereof *to prepare a medicament* for reducing the risk of occurrence of a cardiovascular event in a dialysis patient", (emphasis added). Accordingly, the Examiner interprets the claim to define a process of preparing a medicament containing fosinopril or a pharmaceutically acceptable salt thereof.

Claims 2-14 are directed to elements that are not further limiting to such a preparation process because, rather than being directed to either the process step of preparing the medicament or the medicament itself, the claims are directed to either an intended patient, a disease condition suffered by such patient or to the dialysis procedure. Accordingly, claims 2-14 do not further limit the subject matter of a previous claim.

In order to overcome this objection, Applicants are required to cancel claims 2-14 or else rewrite/amend the claims as appropriate.

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Claim Rejection - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Accordingly, for the reason above, the claims are deemed properly rejected.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 provides for the use of fosinopril or a pharmaceutically acceptable salt thereof to prepare a medicament. However, because the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. In order to properly overcome this point of

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rejection, Applicants should amend the appropriate claim(s) to include one or more steps for accomplishing the claim objective of preparing a medicament.

As noted above, for the purpose of examination, the present claims are interpreted as being directed to a process of preparing a medicament. Applicants are advised that such claims have fixed the inventive subject matter for which examination is sought by original presentation. Should Applicants attempt to define in a subsequent amendment an invention that is patentably distinct from the presently claimed process of producing a preparation, (e.g., by presenting claims to either a pharmaceutical preparation or a method of treating one or more disease conditions in a patient suffering therefrom), the Examiner will follow the guidance provided as per 37 C.F.R. § 1.145, "Subsequent presentation of claims for different invention" and MPEP § 821.03, "Claims for Different Invention Added After an Office Action".

Accordingly, for the reasons above, the claims are deemed properly rejected.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Grover et al., (U.S. Patent No. 4,931,464, cited by the Examiner).

Grover et al. teach a method for preparing an orally acceptable pharmaceutical composition, (a.k.a., preparation), which comprising admixing fosinopril sodium with various pharmaceutically acceptable carriers/diluents, (see cols. 5, lines 22-28, cols. 5-6 at "Example 2",

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and col. 6, lines 15-16, "Similar tablets can be prepared by employing fosinopril sodium...").

The dosages taught by the patentees are "about 0.01 mg/kg to about 100 mg/kg and preferably from about 0.1 mg/kg to about 25 mg/kg to about 25 mg/kg...", (col. 4, lines 53-54) and "from about 0.1 to about 500 mg. preferably from about 125 to about 200 mg., and more preferably from about 25 to about 150 mg...", (col. 4, lines 65-67). These ranges, especially when taken with the modifier "about" would have placed in the possession of the public those ranges or amounts presently claimed by Applicants in claims 17, ("from 5 to 20 mg of fosinopril or a pharmaceutically acceptable salt thereof"), 18, ("a daily administration of about 0.01 mg/kg to about 25 mg/kg of fosinopril or a pharmaceutically acceptable salt thereof") and 19, ("about 10 mg of fosinopril or a pharmaceutically acceptable salt thereof").

The elements of claims 2-14, unlike those of claims 15-19, are not material elements or limitations of the presently claimed process of preparing a medicament as such elements are directed to the patient, a dialysis procedure and/or a disease conditions suffered by the patient, i.e., intended functions or use. Such elements do not impart any further material or otherwise distinctive feature to the claimed preparation process that is described by Grover et al. and thus do provide patentable moment to the claimed subject matter.

Accordingly, for the reasons above, the claims are deemed properly rejected.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grover et al., (U.S. Patent No. 4,931,464, cited by the Examiner), for the reasons above, which reasons are here incorporated by reference.

The difference between the above and the claimed subject matter lies in that Grover et al. do not specify the exact same dosage ranges or specific dosage amount as in present claims 17-19.

However, the difference between the subject matter sought to be patented and the prior art is such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the patentees provide dosage guidance that would embrace the presently claimed dosage ranges and/or amount and it has been held that "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. '[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

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optimum or workable ranges by routine experimentation.' *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (see MPEP 2144.05(II)).

Also, the determination of the optimum dosages to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art and such determination would have been made in accordance with a variety of factors and in due course of routine experimentation. These factors would have included the age, weight, sex, diet and medical condition of the patient(s), severity of the disease, pharmacological considerations such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed and whether the compound is administered a part of a drug combination. Thus, the dosages that would have actually been produced in the preparation method of Grover et al. would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent the dosages that would have been determined by the skilled artisan or else dosages that provide some result in the claimed process of preparing a medicament that would not have been expected by the artisan.

Accordingly, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

References Cited by the Examiner

The additional references cited by the Examiner on the attached form PTO-892 and not relied upon herein have been included to show the general state of the art concerning either (i) the treatment of various diseases, such as congestive heart failure in renal failure patients undergoing dialysis through the administration of angiotensin converting enzyme (ACE) inhibitors, (see Moskowitz, U.S. Patent Application Publication No. 2003/0040509 at the

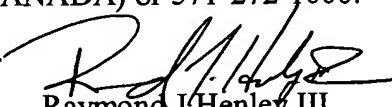
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abstract and paragraphs [0005], [0006], [0017], [0022], [0026], [0027], [0049], [0058], [0125], [0170] and claims 1, 6 and 9 at page 14), or (ii) the concept that atherosclerosis is involved in the pathogenesis of unstable angina pectoris, myocardial infarction or sudden death, (see paragraph [0005]).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Raymond J. Henley III
Primary Examiner
Art Unit 1614

June 16, 2006